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USE OF ALGINIC ACID OR ITS SALTS OF Polyvalent metals IN THE MANUFACTURE OF GÉLULES.

The invention relates to the use in manufacture of gélules of pharmaceutical use of alginic acid or its salts of certain polyvalent metals making it possible to obtain gélules which are not surbedded in the stomach, but only in the intestine and are refer for that gastro-r8sistantes. It concerns with ticuliàrument the use of calcium alginate.

The gélules normally consist of a film of a substance shaper, in general in two parts which one can associate so that they contain the medicament which is generally a powder. The presentation in gélules makes it possible not to put in contact of the mouth a substance, and, ds more, to there release the active principle or one wishes that it intervenes.

The gélules are normally manufactured out of gelatine which is surbedded rapidly in the stomach; they must present certain characteristics at the same time flexibility and ds resistance for enters handled by the machines to conditfonner to large rate without there being deterioration.

The principle of manufacture consists in using an aqueous solution in which one soaks moulds which retain a layer of solution giving with drying gelatine envelopes which are removed and adapt to form the gélules.

Other components than the gelatine can be added to this one to perfect the qualities of the gélules.

In certain treatments, it would be appropriate that the active product of the gélule 'is not ibéré in the stomach but only in the intestine; it appeared that the addition to the gelatine of certain substances would not make it possible to delay its surbeds lies; in the same way the test of noncontestable substances by the acidity or pepsin, diastase of gastric juice, does not have given the results discounts, the resistant substances remaining in the intestinal ways.

- ▲ top The applicant found, and this constitutes the invention, which one obtained a substance allowing the gélule not to be degraded in the stomach all while being it with his arrival in flax testin.

This substance is the alginic acid or its salts of certain polyvalent metals.

The alginic acid is a polysaccharide, made up of a sequence of acids mannuronic and guluronic, insoluble in water; there exists with the natural state in algae such as the laminar ones where it is especially ous form of calcium alginates which are also insoluble in water; the alginic acid is mainly used in the form of alkaline alginate, of sodium particu lièrsment: the alkaline alginates are with the dry state of the powders which give to low concentration in lteau more or less viscous solutions which one uses the properties in various applications. Other salts of bivalent metals than magnesium or great valence are on the other hand insoluble in the water with which they can produce gels.

This property was uses to obtain from reconstituted Pruitts or vegetables and to carry out films allowing for example the coating of the fish front congelation. In all these cases the alginate of metal Bi or polyvalent insoluble remainder with ltétat; it is mainly the calcium alginate besides which is used because of harmlessness of calcium.

According to the invention, one noted that by using for the clothes industry of the gélules the alginic acid or a salt of certain polyvalent metals, one obtained gdulules which were not destroyed by gastric juice and were thus by consequence gastro r8sistantes and which on the other hand was rapidly destroyed in the intestine whereas one could think that they would preserve their resistance.

The polyvalent metal which appears most suitable is the calcium but of other metals can be considered insofar as it is not necessary to fear their ingestion; it can be the case of aluminium; one will thus retain particularly the use of aluminium or calcium alginates.

The clothes industry of the gélules can be obtained on the basis of an aqueous alkaline alginate solution in which one soaked the moulds: closed tubes in the shape of fingers, in order to obtain a enve magnifying glass of this alginate, then year soaking in a solution of an acid or a salt of suitable polyvalent metal and while drying

While soaking in a solution of an acid, there is basic exchange between alginate and the acid with formation of alginic acid and salt of the alkali metal; while soaking in a solution of a salt of calcium or aluminium, there is basic exchange between alginate and the salt of calcium or aluminium with formation of alginate-of calcium or aluminium.

The alginate, like the alginic acid, can not be utili single, but with adjuvants of plasticity or components adapted with the manufacture of gélules, for example the gelatine; one can also coat by steeping with the gélules with gelatine which bring their propri8t8s mechanical own, or then coat with gXlatine the goules with alginic acid or alginate.

The invention will be included/understood better using the following examples

Example 1: calcium alginate gélules.

One used a solution of the following composition

Sodium alginate low viscosity 4 G

Sorbitol 40 G

Water 60 G in which one plunged pendent 30 seconds the moulds that one then plunged pendent 10 seconds in a solution 0,1 M of calcium chloride; after drying 90 minutes in the air with 300C, one recovers the elements of gélules. The chemical analysis gives an average composition of calcium alginate 90% and sodium alginate 10%.

These elements were immersed in a solution representing juice stomacal, of the following composition:

sodium chloride 2 G

pepsin 5 G

hydrochloric acid concentrated 5 ml

water q.s. for 1 l

The solution is maintained with 370C. After 3 hours of immersion it is noted that there is no délitement; by continuing the immersion, one makes the same observation at the end of 12 midnight.

An analysis of the gélules after three hours of immersion gives the following average composition: Alginic acid: 95%, alginate sodium: 2,5%, alginate of calcium: 2,5 %. The passage of alginates to the insoluble form alginic acid still does not allow délitement.

The elements of gélules having remained 3 hours or 24 hours were then immersed in the artificial solution representing intestinal juice, of the following composition:

phosphate monopotassic 6,8 G

pancreatin 10 g

soda 0,2 solution NR 190 ml

water q.s. for 1 l

This solution is maintained at 37 C. One observes a rapid decomposition of the elements of gélules which would allow the release of the active products in 10 minutes and is total in 30 minutes.

The gélules satisfy the specifications of Pharmacopfes French and American.

▲ top Example 2: gélules of alginic acid.

One used at the beginning the same sodium alginate solution as in the preceding example; the moulds after to be plunged 30 seconds in this solution were pendent to it the même time in a solution 0,5 NR of hydrochloric acid then dried. The chemical analysis gives ones average composition of 50% of alginic acid and sodium alginate 50%.

Gelation is slower than for calcium alginate and the salt exchange of sodium - acid is less pushed than Ité- changes sodium salt - salt of calcium, which decreases the gastrorésistance.

Example 3: aluminium alginate gélules.

One used at the beginning the same sodium alginate solution as in example 1; the moulds after to have been plunge 30 seconds in this solution were to it 30 seconds in a solution at 5% in aluminium sulphate weight whose pH was brought back to 3,8 by addition of soda then dried. One obtains gélules which satisfy the specifications of Pharmacopdes French and American

Example 4: calcium-gelatine alginate gélules

One used a solution containing 2% in weight of sodium low viscosity alginats and gelatine 18%; the moulds are plunged pendent 30 seconds in this maintained solution with pendent SOOC then 10 seconds in a solution 1 M of chloride calcium and dried. The gélules obtained satisfy the spécifica- tions Pharmacopeias French and American

Example 5: gelatine gélules covered with a calcium alginate film.

There are tempered the moulds, successively, pendent 30 seconds in a solution at 20% in maintained gelatine weight with 600C, then pendent 30 seconds in a solution of the composition sui- praises: Sodium alginate: 4 G, sorbitol: 40 G, water: 60 G and finally pendent 10 seconds in a solution 1 M of calcium chloride; after s8chage one obtains gélules which satisfy the specifications of both also PharmacopBes.

The use of alginic acid or insoluble alginates in water thus makes it possible to obtain gastro-resistant gélules being able to be used for ingestion of medicinal compositions which should not be released in the stomach.

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REIIENDICATIONS

1 - Gélules resistant with the attack of gastric juices, characterized in that they are made up of alginic acid or an insoluble alginate in water.

2 - Gélules according to claim 1 characterized in that they are made of calcium alginate.

3 - Gélules according to claim 1 characterized in that they are made up of aluminium alginate.

4 - Gélules according to one of the preceding claims characterized in what gelatine is associated the alginic acid or insoluble alginate in top water.

5 - Gélules, resistant with the attack of the juices gastri ques, characterized in that it are made up of gelatine coated with alginic acid or an insoluble alginate in water.

6 - Gélules, resistant with the attack of the gastric juices, characterized by what they are made up of alginic acid or insoluble alginate in water, gelatine bituminous mix.

7 - Gélules according to claims' 5 or 6 caracté- rized in what the alginate is a calcium alginate.

8 - Gélules according to claims' 5 or 6 caracté- rized in what the alginate is an aluminium alginate.

9 - Use of the gélules according to one of the preceding reven dicatinne to the clothes industry of gélules of pharmaceutical and medicinal use.

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? Title: **FR2521428A1: UTILISATION D'ACIDE ALGINIQUE OU DE SES SELS DE METAUX POLYVALENTS DANS LA FABRICATION DE GELULES**

? Derwent Title: Gastro:resistant capsules - mfd. from alginic acid or water-insoluble alginate [Derwent Record](#)

? Country: **FR France**

? Kind: **A1 APPLICATION FOR PATENT OF INVENTION** (See also: [FR2521428B1](#))



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? Inventor: **FRANCOISE LERAT ET ROBERT RIZZOTI;**

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Gazette date	Code	Description (remarks)	List all possible codes for FR
1999-12-03	ST -	Lapsed	
1988-08-12	BR +	Restoration of rights	
1988-05-13	CD	Change of name of nomination	
1988-05-13	TP	Transmission of property	
1988-03-04	AR	Application made for restoration	
1987-12-24	ST -	Lapsed	

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? Family:

PDF	Publication	Pub. Date	Filed	Title
<input checked="" type="checkbox"/>	FR2521428B1	1986-03-07	1982-02-18	UTILISATION D'ACIDE ALGINIQUE OU DE SES SELS DE METAUX POLYVALENTS DANS LA FABRICATION DE GELULES
<input checked="" type="checkbox"/>	FR2521428A1	1983-08-19	1982-02-18	UTILISATION D'ACIDE ALGINIQUE OU DE SES SELS DE METAUX POLYVALENTS DANS LA FABRICATION DE GELULES
2 family members shown above				

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References:

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PDF	Patent	Pub.Date	Inventor	Assignee	Title
<input checked="" type="checkbox"/>	US5508022	1996-04-16	Clement; Anne	Helena Rubinstein Inc.	Gelled emulsion particles and compositions in which they are present

	US5208028	1993-05-04	Clement; Anne	Helena Rubinstein, Inc.	Gelled emulsion particles and compositions in which they are present
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Other Abstract Info: None



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